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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,842	05/16/2006	Wai Ming Wong	P001.006.NPEUS	7752

56374 7590 03/26/2008

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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
03/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,842	WONG ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,8,10-14 and 21-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,8,10-14 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The sequence listing filed February 5, 2008 is approved.

2. The amendments to the specification filed February 5, 2008 (see page 10/Appendix A of the response) have not been entered because they are not in compliance with 37 CFR 1.121(b). In particular, the amendment instructions do not unambiguously identify the location of the paragraph to be replaced and of the paragraph to be added, as required by 37 CFR 1.121(b)(1)(i). The amended paragraphs are identified by paragraph numbers, which paragraph numbers are not present in the substitute specification filed July 12, 2007. In the replacement paragraph identified as "[0002]", no changes to the paragraph are marked. In the new paragraph identified as "[0002.1]", the text of the paragraph should not be underlined. See 37 CFR 1.121(b)(1)(iii).

Note that if the new paragraph identified as "[0002.1]" had been entered, it would have been objected to for lack of clarity. It is not clear what the paragraph present in the patent specification will be referring to when it mentions the sequence listing "submitted herewith". It is not clear if this refers to, e.g., the sequence listing originally filed with the application, the sequence listing filed as of the date of the amendment, etc.

Page 6 of the response filed February 5, 2008 contains an amendment to the Abstract, an amendment to page 35 of the specification, and an amendment to "cancel the amendment filed in July 12 2007". None of these amendments have been entered because they were not present in a section beginning on a separate sheet, i.e. separate from the Remarks. See 37 CFR 1.121(h). Changes to the Abstract were not marked by underlining and strikethrough, as required by 37 CFR 1.121(b)(1)(ii). The amendment to "cancel the amendment filed in July 12 2007" also is not entered because there is no provision in 37 CFR 1.121 for cancelling an amendment. Compare 37 CFR 1.121(b)(4). Changes to the specification must be made, e.g., by submission

of replacement or new paragraphs or by instructions to delete particular paragraphs, as set forth in 37 CFR 1.121(b). It is also unclear as to what was intended by this particular amendment instruction. Was the entire substitute specification filed July 12, 2007 to be canceled? Were the amendments to the claims and the abstract also to be canceled? The amendment instruction is ambiguous at best.

3. Applicants' response filed February 5, 2008 included a "Listing of Claims (Clean Copy)". There is no provision in the amendment rules for the submission of a clean copy of the claim amendments. Further, submission of two listings of claims makes it unclear as to which listing is intended to be the official listing of claims to be considered by the examiner. A clean copy of the claim amendments must not be submitted in any further amendments in this application

4. The abstract of the disclosure is objected to because more detail as to the particular pharmaceutical uses contemplated by Applicants is necessary. Further, a SEQ ID NO must be inserted after the amino acid sequence recited in the abstract. See 37 CFR 1.821(d). Correction is required. See MPEP § 608.01(b).

This objection to the abstract would have been overcome had the proposed new abstract at page 6 of Applicants' response been submitted in a form in which it could have been entered into the application.

5. The disclosure is objected to because of the following informalities: A SEQ ID NO must be inserted after each amino acid sequence recited in the specification which is subject to the sequence disclosure rules. See 37 CFR 1.821(d). At page 35, line 7, the patent number is

incorrect (compare the patent number at line 13), and the inventor name is misspelled. Appropriate correction is required.

As noted in section 2 above, the amendments to the specification filed February 5, 2008 have not been entered. It should be noted that Applicants did not propose any response to the first-listed objection in the above paragraph, i.e. the lack of SEQ ID NOS after each occurrence of "Isoleucyl-valyl-threonyl-asparaginyl-threonyl-threonine" and "IVTNTT" in the specification.

6. The amendment filed July 12, 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The incorporation by reference to the provisional application inserted into the first paragraph of the specification is new matter, because the incorporation by reference statement was not present in the application as originally filed. See MPEP 201.11(III), first paragraph, and (III)(F), last paragraph.

Applicant is required to cancel the new matter in the reply to this Office Action.

As noted in section 2 above, the amendments to the specification filed February 5, 2008 have not been entered.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-5, 8, 10-14, and 21-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a hexapeptide comprising the amino acid sequence of SEQ ID NO:1/a peptide consisting of the amino acid sequence of SEQ ID NO:1,

does not reasonably provide enablement for all peptides corresponding to portions of Applicants' SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150 (CCPA 1977) and have been adopted by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. With respect to (1), the nature of the invention is pure peptides consisting of "an" amino acid sequence of SEQ ID NO:1, and their use to reduce symptoms of a viral disease and as immuno-stimulants. Because of the use of the indefinite article "an", Applicants' claims embrace peptides which correspond to portions of SEQ ID NO:1, e.g., embrace dipeptide, tripeptide, tetrapeptide, and pentapeptide fragments of SEQ ID NO:1. With respect to (2), while pure peptide fragments of SEQ ID NO:1 are taught in the prior art (see, e.g., the Bouchonnet et al article applied in section 9 below), they are not taught to have activity in reducing the symptoms of a viral disease or as immuno-stimulants. With respect to (3), the relative skill in the art is high. With respect to (4), the peptide therapeutic arts are in general unpredictable. There is no expectation in the art than any and all fragments of a peptide will possess the same therapeutic activities of the peptide. With respect to (5), the claims are relatively broad because, as noted above, the use of the indefinite article "an", Applicants' claims

embrace peptides which correspond to portions of SEQ ID NO:1, e.g., embrace dipeptide, tripeptide, tetrapeptide, and pentapeptide fragments of SEQ ID NO:1. With respect to (6) and (7), the only working examples involve the hexapeptide consisting of SEQ ID NO:1. Fragments of this hexapeptide are not tested for activity, and no mechanism of action or structure-activity relationship is disclosed which provides a basis for predicting that fragments of the hexapeptide will possess the same activity as the hexapeptide. With respect to (8), in the absence of any working examples or proposed mechanism of action or structure-activity relationship, one skilled in the art would be limited to randomly testing fragments of the hexapeptide in order to try and achieve virus-treating or immuno-stimulating results. Such random testing constitutes undue experimentation. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1, 3-5, 8, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by the Bouchonnet et al article (Biol. Mass Spec., Vol. 21, pages 576-584). The Bouchonnet et al article teaches the dipeptide Val-Thr, purchased from Sigma Chemical Company, combined with a 1:1 mixture of isopropanol and ultrapure water, and subjected to mass spectrometry. See, e.g., page 576, column 2, first paragraph; page 577, column 1, first full paragraph; and page 578, Table 2. The dipeptide "Val-Thr" of the Bouchonnet et al article consists of "an" amino acid sequence of Applicants' SEQ ID NO:1, i.e. consists of the amino acid sequence found at residues 2-3 of Applicants' SEQ ID NO:1. Note that Applicants' use of the indefinite article "an" means that the claims embrace any peptide corresponding to any portion of SEQ ID NO:1. With

respect to instant claims 3-5, in view of the similarity in structure between the dipeptide of the Bouchonnet et al article and the peptides recited in Applicants' claims, inherently the former will reduce symptoms of a viral disease such as hepatitis B infection and will have immuno-stimulating properties to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptide of the Bouchonnet et al article and Applicants' claimed peptide to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than the peptide of the Bouchonnet et al article. With respect to instant claims 8 and 10, note that an intended use limitation, i.e. "pharmaceutical", does not impart patentability to product claims where the product is otherwise anticipated by or obvious over the prior art. With respect to instant claim 10, the 1:1 mixture of isopropanol and ultrapure water taught by the Bouchonnet et al article corresponds to Applicants' pharmaceutically acceptable carrier.

10. Applicant's arguments filed February 5, 2008 have been fully considered but they are not persuasive.

If Applicants were to amend their claims to recite, e.g., "A pure peptide consisting of the amino acid sequence of SEQ ID NO:1", or "A pure hexapeptide comprising the amino acid sequence of SEQ ID NO:1", then the above rejections under 35 U.S.C. 102(b) and 112, first paragraph, would be overcome.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
March 28, 2008